

1FW

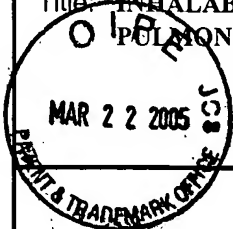
**TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT**  
(Under 37 CFR 1.97(b) or 1.97(c))

Docket No.  
3818.02-5

In Re Application Of: **ALAN BRUCE MONTGOMERY**

Application No.	Filing Date	Examiner	Customer No.	Group Art Unit	Confirmation No.
10/613,639	JULY 3, 2003	HAGHIGHATIAN, MINA	23308	1616	4624

Title: **INHALABLE AZTREONAM LYSINATE FORMULATION FOR TREATMENT AND PREVENTION OF PULMONARY BACTERIAL INFECTIONS**



Address to:  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**37 CFR 1.97(b)**

1. ☒ The Information Disclosure Statement submitted herewith is being filed within three months of the filing of a national application other than a continued prosecution application under 37 CFR 1.53(d); within three months of the date of entry of the national stage as set forth in 37 CFR 1.491 in an international application; before the mailing of a first Office Action on the merits, or before the mailing of a first Office Action after the filing of a request for continued examination under 37 CFR 1.114.

**37 CFR 1.97(c)**

2. ☐ The Information Disclosure Statement submitted herewith is being filed after the period specified in 37 CFR 1.97(b), provided that the Information Disclosure Statement is filed before the mailing date of a Final Action under 37 CFR 1.113, a Notice of Allowance under 37 CFR 1.311, or an Action that otherwise closes prosecution in the application, and is accompanied by one of:
- ☐ the statement specified in 37 CFR 1.97(e);
- OR**
- ☐ the fee set forth in 37 CFR 1.17(p).

**TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT**  
(Under 37 CFR 1.97(b) or 1.97(c))

Docket No.  
3818.02-5

In Re Application: **ALAN BRUCE MONTGOMERY**

Application No.	Filing Date	Examiner	Customer No.	Group Art Unit	Confirmation No.
10/613,639	JULY 3, 2003	HAGHIGHATIAN, MINA	23308	1616	4624

Title: **INHALABLE AZTREONAM LYSINATE FORMULATION FOR TREATMENT AND PREVENTION OF PULMONARY BACTERIAL INFECTIONS**

**Payment of Fee**

(Only complete if Applicant elects to pay the fee set forth in 37 CFR 1.17(p))

- ☐ A check in the amount of \_\_\_\_\_ is attached.
- ☒ The Director is hereby authorized to charge and credit Deposit Account No. 16-1331 as described below.
- ☐ Charge the amount of \_\_\_\_\_
- ☐ Credit any overpayment.
- ☒ Charge any additional fee required.
- ☐ Payment by credit card. Form PTO-2038 is attached.

**WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.**

**Certificate of Transmission by Facsimile\***

I certify that this document and authorization to charge deposit account is being facsimile transmitted to the United States Patent and Trademark Office (Fax. No. \_\_\_\_\_)

\_\_\_\_\_  
(Date)

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Typed or Printed Name of Person Signing Certificate

**Certificate of Mailing by First Class Mail**

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)] on

MARCH 17, 2005

\_\_\_\_\_  
(Date)

\_\_\_\_\_  
Signature of Person Mailing Correspondence

MELINDA TOMPKINS

\_\_\_\_\_  
Typed or Printed Name of Person Mailing Certificate

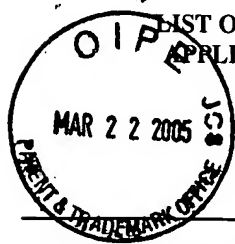
**\*This certificate may only be used if paying by deposit account.**

\_\_\_\_\_  
Signature

Dated: **MARCH 17, 2005**

**HANA VERNY (REG. NO. 30,518)**  
**PETERS, VERNY, JONES, SCHMITT & ASTON, LLP**  
**425 SHERMAN AVENUE, SUITE 230**  
**PALO ALTO, CA 94306**  
**TELEPHONE: (650) 324-1677**  
**FACSIMILE: (650) 324-1678**

CC:



FOR PTO-1449 (Modified)

LIST OF PATENTS AND PUBLICATIONS FOR  
APPLICANTS INFORMATION DISCLOSURE  
STATEMENT

SUPPLEMENTAL

(Use several sheets if necessary)

ATTY. DOCKET NO.

3818.02-5

SERIAL NO.

10/613,639

APPLICANT : ALAN BRUCE MONTGOMERY

FILING DATE : JULY 3, 2003

GROUP 1616

REFERENCE DESIGNATION

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER							DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE	
	F2	6	5	1	8	2	3	9	02/2003	KUO, ET AL.	514	2		
	G1	5	8	7	5	7	7	6	03/1999	VAGHEFI	128	203.15		
	H1	4	8	8	8	9	9	8	12/26/1989	BUZZA, ET AL.	73	864.21		
	I1	5	9	9	4	3	4	0	11/30/1999	MAITI, ET AL.	514	192		
		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
													YES	NO
	M1	WO	01	3	4	2	3	2	5/17/2001	PCT	11	00	X	
	N1	EP	0	2	9	7	5	8 0	1/20/1999	EP	417	12	X	

OTHER

ART (Including Author, Title, Date, Pertinent Pages, Etc.)

	T1		John A. Bosso, et al., Efficacy of Aztreonam in Pulmonary Exacerbations of Cystic Fibrosis, <u>The Pediatr. Infect. Dis. J.</u> , 6:393-397 (1987).
	U1		James L. Cook, M.D., Gram-Negative Bacillary Pneumonia in the Nosocomial Setting, <u>The American Journal of Medicine</u> , 88:3C-34S-37S.
	V1		A. Boccazzi, et al., The Pharmacokinetics of Aztreonam and Penetration into the Bronchial Secretions of Critically Ill Patients, <u>Journal of Antimicrobial Chemotherapy</u> , 23:401-407 (1989).
	W1		Harold C. Neu, M.D., Aztreonam Activity, Pharmacology and Clinical Uses, <u>The American Journal of Medicine</u> , 88:3C-2S-3C-6S.
	X1		John J. LiPuma, MD, <i>Burkholderia cepacia</i> , Management Issues and New Insights, <u>Clinics in Chest Medicine</u> , 19/3:473-486 (September 1998).
	Y1		Stephen C. Aronoff, et al., <i>In Vitro</i> Activities of Aztreonam, Piperacillin, and Ticarcillin Combined with Amikacin Against Amikacin-Resistant <i>Pseudomonas aeruginosa</i> and <i>P. cepacia</i> Isolates from Children with Cystic Fibrosis, <u>Antimicrobial Agents and Chemotherapy</u> , 25/2:279-280 (February 1984)).
	Z1		John A. Bosso, et al., <i>In Vitro</i> Activities of Combinations of Aztreonam, Ciprofloxacin and Ceftazidime Against Clinical Isolates of <i>Pseudomonas aeruginosa</i> and <i>Pseudomonas cepacia</i> from Patients with Cystic Fibrosis, <u>Antimicrobial Agents and Chemotherapy</u> , 34/3:487-488 (March 1990).
	TT		John M. Matssen, et al., The Use of Aztreonam in the Cystic Fibrosis Patient, <u>Pediatr. Infect. Dis. J.</u> , 8/9:S117-S119 (1989).
	UU		Lisa Saiman, MD, Antimicrobial Resistance Among <i>Burkholderia</i> , <i>Stenotrophomonas</i> and <i>Alcaligenes</i> isolates Studied by the CF Eferal Center for Susceptibility and Synergy Testing, 1998 Cystic Fibrosis Conference, Symposium Session Summaries, 118-119 (1998).
	VV		Preston W. Campbell III, MD., et al., Use of Aerosolized Antibiotics in Patients with Cystic Fibrosis, Consensus Conference, pp. 775-789 (September 1999).
	WW		Dapena Fernandez J., et al., Inhaled Aztreonam Therapy in Patients with Cystic Fibrosis Colonized with <i>Pseudomonas aeruginosa</i> , <u>Spanish Annals on Pediatrics</u> , 40/3 (1994).
	XX		Gerald C. Smaldone, et al., Aerosolized Antibiotics: Current and Future, <u>Respiratory Care</u> , 45/6:667-675 (June 2000).
	YY		Thomas G. O'Riordan, MD, Inhaled Antimicrobial Therapy: From Cystic Fibrosis to the Flue, <u>Respiratory Care</u> , 45/7:836-845 (July 2000).
	ZZ		Robert G. Bell, et al., Stability of Intravenous Admixtures of Aztreonam and Cefoxitin, Gentamicin, Metronidazole, or Tobramycin, <u>American Journal of Hospital Pharmacy</u> , 43:1444-1453 (June 1986).
	TT1		Michael J. James, et al, Stability of Intravenous Admixtures of Aztreonam and Ampicillin, <u>American Journal of Hospital Pharmacy</u> , 42:1095-1100 (May 1985).
	UU1		Desppina Daisy Frangolias, et al., <i>Burkholderia cepacia</i> in Cystic Fibrosis, <u>Am J of Respir Crit Care Med.</u> , 160:1572-1577 (1999).
	VV1		Diane H. Johnson, et al., Aztreonam, <u>Medical Clinics of North America</u> , 79/4:733-743 (4 July 1995).

	WW 1	Woo, M.S., et al., Use of Aerosolized Aztreonam in CF Lung Transplant Patients Colonized With <i>Burkholderia cepacia</i> , 2002 Cystic Fibrosis Conference, p. 322:419
	XX1	Petra Borsje, MD, et al., Aerosol Therapy in Cystic Fibrosis: A Survey of 54 CF Centers, <u>Pediatric Pulmonology</u> , 30:368-376 (2000).
	YY1	Rafael Canton, PD, PhD, et al., Lung Colonization with <i>Enterobacteriaceae</i> Producing Extended-Spectrum $\beta$ -Lactamases in Cystic Fibrosis Patients, <u>Pediatric Pulmonology</u> , 24:213-217 (1997).
	ZZ1	S. Ballester, et al., <i>Stenotrophomonas maltophilia</i> in Cystic Fibrosis Patients, 20 <sup>th</sup> European Cystic Fibrosis Conference, Brussels, Belgium, pp. 18-21 (June 1995).
	TT1	Sira Carrasco, et al., The General Approach to Cystic Fibrosis Pulmonary Infection in Spain, <u>Cystic Fibrosis Pulmonary Infections: Lessons From Around The World</u> , Chapter 18, pp. 223-230 (1996).

EXAMINER

DATE CONSIDERED

**EXAMINER:** Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

PVJS CASE: 3818.01-1 (HV)